REMARKS

I. Status of the Application

This paper responds to a final Office action mailed on February 28, 2005, which rejected claims 1-15. Following an earlier non-final Office Action, Applicant filed a response on December 13, 2004, which amended claims 1-3, 5-10, and 13-15. The application was originally filed with claims 1-15. This paper amends claim 14, cancels claim 15 without prejudice or disclaimer, and adds claim 16. Therefore, claims 1-14 and 16 are currently under consideration in the present application. Applicant respectfully requests reconsideration of the pending claims in view of the above amendment and the following remarks. By action taken here, Applicant does not intend to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

II. Amendment of Claim 14 and New Claim 16

Applicant has amended claim 14 so that the percentage of gabapentin lactam or pregabalin lactam is expressed as "weight/weight" as in original claim 14. Applicant has also added new claim 16, which includes the limitations of claim 15, but corrects grammar and punctuation. Applicant submits that the amendment of claims adds no new matter.

III. Rejection of Claim 15 Under 35 USC § 112 ¶ 2

The Office action rejected claim 15 under 35 USC § 112, paragraph 2, as allegedly being "unclear." As described above, Applicant has canceled claim 15 and added new claim 16, which corrects grammatical informalities in claim 15. Therefore, Applicant respectfully requests withdrawal of the rejection.

IV. Rejection of Claims 1-15 Under 35 U.S.C. § 112 ¶ 1

The present Office action rejected claims 1-15 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. According to the Office Action, claims 1-15 do "not reasonably provide enablement for said composition when it contains a polyhydric alcohol." The Office action contends "WO 99/59573 (page 59, Table 4) discloses that the presence of a polyhydric alcohol in an aqueous gabapentin solution increases lactam formation." Applicant respectively submits that all of the pending claims are enabled. Applicant agrees that WO 99/59573 shows that xylitol increases lactam formation in certain instances. However, the compositions containing xylitol—samples "e" and "f" in Table 4—do not fall within Claims 1-14 and 16 of the present application, and therefore, Applicant respectfully submits that the claims are properly enabled.

V. Rejection of claims 1-15 Under 35 U.S.C. § 103

The present Office action rejected claims 1-15 under 35 U.S.C. § 103 as being unpatentable over WO 99/58573. According to the prior Office Action, which has been incorporated into the final Office action, "WO 99/59573 (page 50, lines 7-21, pages 58-61, Examples 2 and 3) discloses a liquid composition of a GABA analog comprising a polyhydric alcohol containing 2-6 carbon atoms. It discloses the use of a sweetening agent and a flavoring agent on page 50. The examples further disclose formation of the lactam degradation product is limited by the addition of the polyhydric alcohol." Applicant respectfully submits that claims 1-14 and 16 are patentable over WO 99/59573 and all other references cited in the case.

In a prior response, Applicant amended all of the independent claims so that they now recite that the one or more polyhydric alcohols comprise at least 25% weight/volume of the composition (claim 14) or about 25% to about 75% weight/volume of the composition (claims 1, 6, 9, and 10). Neither WO 99/59573 nor any of the other references cited in the Office Action teaches or suggests these limitations, and therefore, Applicant submits the references cannot anticipate claims 1-14 and 16.

Furthermore, Applicant submits that WO 99/58573 cannot render the claims obvious. As noted in the application, Applicant has discovered that a GABA analog can be formulated in a stable liquid pharmaceutical composition having low levels of a GABA analog lactam when the pH of the composition is about 5.5 to about 7.0 and when the composition includes one or more polyhydric alcohols. See Specification, page 4, lines 4-7, and page 9, lines 7-9. Nothing in WO 99/59573 teaches or suggests that this pH range and the addition of one or more polyhydric alcohols in the claimed amounts would result in a stable liquid pharmaceutical composition containing a GABA analog.

Moreover, WO 99/59573 teaches away from the use of a polyhydric alcohol in pharmaceutical compositions containing a GABA analog. For instance, Example 2 in WO 99/59573 shows that the addition of a polyhydric alcohol (xylitol, sample "e") to an aqueous gabapentin solution increases lactam formation (compare sample "d" and sample "e" in Table 4). The addition of glycine (sample "f") to an aqueous solution of gabapentin and xylitol appears to decrease lactam formation (compare sample "f" with samples "d" and "e" in Table 4). Thus, WO 99/59573 states that Table 4 "shows that gabapentin in its aqueous solution could be similarly prevented from the degradation with lapse of time (the lactam formation) by the addition of glycine, even in the presence of xylitol," i.e., despite the presence of xylitol (emphasis added). According to the final Office action, this argument "is not persuasive, since there is no data in the instant specification to support this assertion."

To support Applicant's assertion that the claimed composition is stable, Applicant has attached to this amendment a declaration under 37 CFR § 1.132. The § 1.132 declaration provides long-term stability data for a pharmaceutical syrup composition currently marketed by Pfizer Inc. The syrup contains gabapentin, two polyhydric alcohols—glycerol and xylitol—artificial flavor, and purified water. Together, the amount of glycerol and xylitol is between 25% and 75% w/v of the total composition, and the pH of the composition is in the range of 5.5 to 7.0. The gabapentin syrup is similar to the liquid pharmaceutical compositions shown in Table 1 of the present application and it falls within the scope of at least claim 1.

The data in Table A, which accompanies the § 1.132 declaration, demonstrate that the gabapentin syrup is stable. For gabapentin syrup samples stored at 5°C for up to 24 months, the lactam concentration was 0.1 % or less, based on weight of gabapentin. Likewise, for gabapentin syrup samples stored at 25°C for 6 months, the lactam concentration was 0.4 % or less, based on weight of gabapentin. These data support Applicant's contention that the claimed compositions are stable.

Finally, Applicant respectfully submits that the Office action's reliance on *In re Aller et al.* for the assertion that "pH limitation is one that is determined by one skilled in the art and does not impart patentability" is misplaced. The Board of Appeals in *In re Aller et al.* held that the appellants were not entitled to a patent on a process for making phenol because they had simply changed the reaction conditions of a process that was otherwise in the prior art and were unable to establish that modifying the reaction conditions of the prior art process achieved unexpected results. Presumably, had the appellants been able to show that increasing the acid concentration led to unexpected results, the Board in *In re Aller et al.* would have ruled in their favor.

Thus, *In re Aller et al.* does not apply to the present application. Unlike the appellants in *In re Aller et al.*, Applicant has discovered that aqueous formulations containing a GABA analog, such as gabapentin, and one or more polyhydric alcohols, such as xylitol, which were thought to be unstable, could be stabilized by limiting the pH and polyhydric alcohol composition to the ranges recited in the claims. This result was completely unexpected and therefore the claims of the present application are patentable under the rule in *In re Aller et al.*

Applicant respectfully submits that claims 1-14 and 16 are patentable over WO 99/59573 and all references cited in the case and, therefore, respectfully requests withdrawal of the rejection.

VI. Conclusion

In view of the foregoing, Applicant respectfully submits that all pending claims are patentable over the prior art of record. If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

Applicant submits that all fees due with respect to the filing of this paper are listed in a RCE transmittal that accompanies this amendment. However, if any other fees are required in connection with this amendment, and such fees have not been identified in the accompanying RCE transmittal, please charge deposit account number 23-0455.

Respectfully submitted,

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Enc: Declaration Under 37 CFR § 1.132 by Majid Mahjour, Ph.D.
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Fee Transmittal